

## PATENT COOPERATION TREATY

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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SJW/46455	<b>FOR FURTHER ACTION</b>		See Form PCT/PEA/416
International application No. PCT/GB2004/004954	International filing date (day/month/year) 24.11.2004	Priority date (day/month/year) 24.11.2003	
International Patent Classification (IPC) or national classification and IPC A61C9/00, A61C19/06			
Applicant RETRACTOTOP LIMITED et al.			
<p>1. This report is the International preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows: 2</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand  26.09.2005		Date of completion of this report  07.12.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer  Roche, O Telephone No. +49 89 2399-2377	



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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

**Description, Pages**

1-10 as originally filed

**Claims, Numbers**

1-10 received on 14.10.2005 with letter of 26.09.2005

**Drawings, Sheets**

1/5-5/5 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing *(specify):*
  - ☐ any table(s) related to sequence listing *(specify):*
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing *(specify):*
  - ☐ any table(s) related to sequence listing *(specify):*

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

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1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
- ☐ the entire international application,
  - ☒ claims Nos. 9,10
- because:
- ☒ the said international application, or the said claims Nos. 9,10 relate to the following subject matter which does not require an international preliminary examination (specify):  
**see separate sheet**
  - ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
  - ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
  - ☒ no international search report has been established for the said claims Nos. 9,10
  - ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
    - the written form ☐ has not been furnished
    - ☐ does not comply with the standard
    - the computer readable form ☐ has not been furnished
    - ☐ does not comply with the standard
  - ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
  - ☐ See separate sheet for further details

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	1-8
	No: Claims	
Inventive step (IS)	Yes: Claims	1-8
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-8
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

No opinion is required for claims 9 and 10 as they relate to methods for treatment of the human or animal body by therapy (rule 67.1(iv) PCT).

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

The document D1 WO 02/102269 A which is regarded as being the closest prior art to the subject-matter of claim 1, shows The document D1 discloses (see paragraphs 02, 26, 71 and figure 15) a dental device (112) comprising a sheath for fitting over a tooth, the sheath carrying a haemostatic agent in at least one region thereof, wherein the sheath comprises a generally cylindrical body having a first end (116+142) open to a cavity and a second end that is closed, and wherein the open end carrying the haemostatic agent.

The subject-matter of claim 1 differs from this known orthodontic bracket in that the closed end is constructed to yield upon application of pressure.

The subject-matter of claim 1 is therefore novel (Article 33(2) PCT).

The problem to be solved by the present invention may therefore be regarded as softening the occlusal pressure applied on the sheath to protect the delicate gingivae around the tooth.

Neither this problem nor the claimed solution are disclosed in the cited prior art.

The solution to this problem proposed in claim 1 of the present application is therefore considered as involving an inventive step (Article 33(3) PCT).

The same reasoning applies, mutatis mutandis, for the subject matter of claim 7.

Moreover, such a dental device is industrially applicable, such that all the requirements of Articles 33(2)-(4) PCT are met.

Dependent claims 2-6 and 8 as such also meet the requirements of Articles 33(2)-(4) PCT

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(SEPARATE SHEET)**

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with respect to novelty and inventive step.

CLAIMS:

1. A dental device comprising a sheath for fitting over a tooth, the sheath carrying a haemostatic agent in at least one region thereof, wherein the sheath comprises a generally cylindrical body having at least a first end and a second end, at least one of said first and second ends presenting a circumferential margin carrying at least part of the haemostatic agent, the at least one end carrying at least part of the haemostatic agent is open to a cavity and the other end is closed, and the closed end is constructed to yield upon application of pressure.
2. A dental device according to claim 1, wherein the cavity progressively narrows from its open end towards the closed end.
3. A dental device according to claim 1 or claim 2, wherein the cavity is dome-shaped at its closed end.
4. A dental device according to any one of the preceding claims, wherein the generally cylindrical body comprises a wall between said first and second ends at least part of the cylindrical wall being stiffened.
5. A dental device according to claim 4, wherein the cylindrical wall is stiffened by application of a suitable non-toxic material.
6. A dental device according to claim 5, wherein the non-toxic material is gelatin.
7. A set of dental devices according to any preceding claim, the devices in the set being of different sizes.
8. A set according to claim 7, wherein the devices are colour coded to denote their respective sizes.
9. A method of inhibiting or preventing gingival bleeding, the method comprising placing over a tooth, a device according to any one of claims 1 to 6.

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10. A method of retracting gingivae, the method comprising placing over a tooth a device according to any one of claims 1 to 6 and, optionally, applying pressure to the device.